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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,119	04/12/2004	Walter Muller	512100-2034	3517

20999 7590 08/25/2009
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
08/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,119	MULLER, WALTER	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The finality of the office action mailed 02/10/2009 has been withdrawn and new action on the merit is hereby issued.

Claims 1-20 are pending and included in the prosecution.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-55 of

copending Application No. 10/835,997 in view of Robbins (US 6,239,180). The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are subject matter as follows: transdermal patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent and method of making the transdermal patch including the steps of dissolving the active agent in amphiphilic solvent, mixing the drug solution with polysiloxane solution to form dispersion, coating the dispersion onto protective liner, removing the solvent of the polysiloxane to form matrix, laminating a backing layer to the dried matrix.

However, the present claims are different from the copending claims because the copending claims not drawn to capsaicin while the present claims recite capsaicin.

Robbins teaches transdermal patch to deliver capsaicin or capsaicin analog that are extremely effective therapy for treating peripheral neuropathic pain for prolonged period of time (abstract; col.2, lines 26-30; col.3, lines 62-65; col.4, lines 12-13).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent dissolved in an amphiphilic solvent as claimed by the copending application '997, and deliver capsaicin taught by Robbins in the microreservoirs claimed by the copending application. One would have been motivated to do so because Robbins teaches that capsaicin or capsaicin analog when delivered in transdermal patch are extremely

effective therapy for treating peripheral neuropathic pain for prolonged period of time. One would reasonably expect formulating transdermal patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising capsaicin or its analogs in an amphiphilic solvent to treat neuropathic pain effectively for prolonged period of time.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection. The present claims recite "capsaicin analog". The specification failed to describe any

"capsaicin analogs" to satisfy the written description requirements. Because the instant specification does not provide written description of what structures are contemplated for such "capsaicin analog", this phrase lacks adequate written description. Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.,* 119 F. 3d 1559, 1568 (Fed. Cir. 1997), cert denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly and Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.,* 249 Supp. 2d 216,225 (W.D.N.Y. 2003).

Applicant has failed to provide any written description for "capsaicin analog" in the instant specification. As such, it is not apparent that Applicant was actually in possession of, and intended to use, within the context of the present invention, any capsaicin analogue at the time the present invention was made. The specification neither provides any analogs required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller (WO 01/01967, translation currently provided) in view of Robbins (US 6,239,180) and Schacht et al. (US 2005/0079206).

Applicant Claims

Applicant claims a topical patch comprising a therapeutic compound-impermeable backing layer, a self-adhesive amine-resistant polysiloxane matrix containing at least 1% by weight, of the therapeutic compound wherein the polysiloxane matrix is a mixture of a polysiloxane of medium tack and a polysiloxane of high tack and the therapeutic compound is capsaicin or a capsaicin analog or mixture thereof, and a protective film to be removed before use, in which

a) the matrix contains liquid microreservoir droplets comprising an amphiphilic solvent, in which the therapeutic compound is dissolved, and

b) the concentration of the therapeutic compound in the microreservoir droplets is between 20 and 90% by weight of the saturation concentration wherein the amphiphilic solvent is a butanediol, 1,3-butanediol, dipropylene glycol, tetrahydrofurfuryl alcohol, diethylene glycol dimethyl ether, diethylene glycol monoethyl ether, diethylene glycol monobutyl ether, propylene glycol, dipropylene glycol, carboxylic acid esters of tri- and diethylene glycol, polyethoxylated fatty alcohols of 6 - 18 C atoms or 2,2-dimethyl-4-hydroxymethyl- 1,3-dioxolane, or mixtures of these solvents. Claim 20 further recite conventional method of making the device.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Muller teaches transdermal therapeutic system on the basis of polysiloxane which contains microreservoirs filled with an active agent and amphiphilic solvent (abstract). The transdermal therapeutic system comprises backing layer impermeable to the active agent, matrix containing microreservoirs containing active agent dispersed in amine resistant polysiloxane polymer, and removable protective liner (page 2, page 4). The amphiphilic solvents include 1,3-butaindiol, dipropylene glycol, tetrahydrofurfuryl alcohol, diethylene glycol monoethyl ether (page 3). Examples showed that the concentration of the therapeutic agent in the amphiphilic solvent is from 1-30%, and forming at least 1% of the total matrix. The microreservoirs further comprise viscosity enhancer agents including cellulose derivatives, hydroxypropyl cellulose, high molecular weight polyacrylic acid (page 4). The polysiloxane matrix comprises tackyfying agent such as silicone oil (page 5). The backing layer is made of polyester or ethylene-vinyl-acetate copolymer (page 5). The therapeutic agents include analgesics (page 5). The reference teaches method for making the device comprising the steps of dissolving the active agent in the amphiphilic solvent and mix the solution with polysiloxane solution, forming dispersion of the active agent, coating the dispersion on a abhesively treated film, removing the solvent to form a matrix, and laminating a backing layer onto the dried matrix (page 3).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Muller teaches suitability of the disclosed transdermal system to deliver analgesics agent, however, the reference does not explicitly teach capsaicin as analgesic active agent dissolved in the microreservoirs.

Although Muller teaches that polysiloxane suitable as matrix for microreservoirs comprising amphiphilic solvent and active agent, however, the reference does not explicitly teach mixture of medium tack polysiloxane and high tack polysiloxane.

Robbins teaches transdermal patch to deliver capsaicin or capsaicin analog that are extremely effective therapy for treating peripheral neuropathic pain for prolonged period of time (abstract; col.2, lines 26-30; col.3, lines 62-65; col.4, lines 12-13).

Schacht teaches transdermal device comprising microreservoirs containing drug in a self adhesive matrix, wherein the matrix is silicone adhesive made of mixture of high tack polysiloxane (BIO-PSA 4301) and medium tack polysiloxane (BIO-PSA 4201) that is advantageous in providing optimum balance between good adhesion and little cold flux (abstract; paragraphs: 0054-0058).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, the prior art at the time of the invention recognized microreservoirs containing therapeutic agent dissolved in amphiphilic solvent within polysiloxane matrix as taught by Muller. The art further recognized capsaicin can be delivered transdermally to treat neuropathic pain as taught by Robbins. Mixture of medium tack polysiloxane

and high tack polysiloxane was also known as advantageous adhesive for transdermal devices at the time of the invention as taught by Schacht.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal therapeutic system comprising a polysiloxane polymer matrix comprising microreservoirs containing analgesic agent dissolved in amphiphilic solvent as taught by Muller, and replace the analgesic agent with capsaicin or capsaicin analog taught by Robbins. One would have been motivated to do so because Robbins teaches that capsaicin or capsaicin analog when delivered in transdermal patch are extremely effective therapy for treating peripheral neuropathic pain for prolonged period of time. One would reasonably expect formulating transdermal patch comprising polysiloxane matrix containing microreservoirs comprising capsaicin or its analogs dissolved in an amphiphilic solvent to treat neuropathic pain effectively for prolonged period of time.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch comprising polysiloxane matrix containing microreservoirs comprising capsaicin or its analogs dissolved in an amphiphilic solvent as taught by the combined teaching of Muller and Robbins, and replace the polysiloxane matrix with matrix comprising mixture of high tack polysiloxane and medium tack polysiloxane as taught by Schacht. One would have been motivated to do so because Schscht teaches that such a mixture is advantageous when used in transdermal patches because it provides optimum balance between good adhesion and little cold flux. One would reasonably expect formulating transdermal device comprising

microreservoirs comprising capsaicin or its analogs dissolved in amphiphilic solvent and the microreservoirs are dispersed in matrix made of mixture of high tack polysiloxane and medium tack polysiloxane wherein the matrix has optimum balance between good adhesion and little cold flux.

The references do not teach the exact concentration of the active agent in the microreservoirs or concentration of microreservoirs in the matrix as claimed by claims 3, 10, 11, 13, 14, the coating weight of the drug containing adhesive on the backing layer as claimed by claims 13 and 14, or the thickness of the backing layer as claimed by claim 15. However, the concentration of the active agent and microreservoirs, coating weight, and thickness of the backing would have been determined by one having ordinary skill in the art without undue experimentation based on the specific individual use. Such variants do not impart patentability of the claims in absence of superior and unexpected results.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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